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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/284,436	06/08/2000	Dosuk D. Lee	04712/02000F	2313
23483	7590	04/08/2004	EXAMINER	
HALE AND DORR, LLP			GEORGE, KONATA M	
60 STATE STREET			ART UNIT	
BOSTON, MA 02109			PAPER NUMBER	

1616

DATE MAILED: 04/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/284,436

Applicant(s)

LEE ET AL.

Examiner

Konata M. George

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 128,130-132 and 135-148 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 128,130 and 135-141 is/are rejected.
- 7) ☒ Claim(s) 131,132 and 142-148 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 April 1999 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claims 128, 130-132 and 135-148 are pending in this application.

Action Summary

1. Examiner acknowledges the cancellation of claims 133 and 134. Therefore any and all rejections directed towards them are withdrawn.
2. Examiner acknowledges the addition of claims 144-148.
3. The rejection of claim 132 under 35 U.S.C. 112, second paragraph is hereby withdrawn as applicant has corrected the dependency issue.
4. The rejection of claims 128 and 136-141 under 35 U.S.C 102(b) as being anticipated by Constantz et al. is being maintained for the reasons stated in the previous office action.
5. The rejection of claims 128, 130-132 and 135-143 under 35 U.S.C. 102(e) as being anticipated by Lee et al. is hereby withdrawn.

Drawings

6. The drawing(s) filed April 12, 1999 are objected to by the Draftsperson under 37 CFR 1.84 or 1.152 for the reasons indicated below. The examiner will require submission of new, corrected drawings when necessary. Corrected drawing must be submitted according to the instructions on the PTO-948 form.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 130 and 135 are rejected under 35 U.S.C. 103(a) as being unpatentable over Constantz et al. (US 5,336,264).

See non-final rejection dated September 16, 2003 for rejection.

The prior art does not teach the specific claimed agents as described in claims 130 and 135.

It would have been obvious to one ordinary skill in the art at the time the invention was made to use any of the claimed agents as described. Column 6, lines 52-58 teach that other proteins associated with other parts of the human or other mammalian anatomy can be employed in the composition. The agents described in claims 130 and 135, i.e. para-thyroid hormone and growth factors are proteins found in human anatomy, which in turn can be used in the present invention.

Response to Arguments

8. Applicant's arguments filed March 18, 2004 have been fully considered but they are not persuasive.

Applicants' argue that the prior art does not teach or suggest the composition containing both an agent which directly or indirectly stimulates osteoclast activity

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(hereafter "agent #1") and a biologically active agent (hereafter "agent #2"). It is the position of the examiner that both agents can be one in the same. As claimed "agent #1" is defined as interleukin-1, transforming growth factor α , tumor necrosis factor, vitamin D metabolites, etc. "Agent #2" is defined as numerous agents some of which may be specific targeting agents, growth factors, vitamins, etc. It is shown that there is some overlaying in the two agents. It is the position of the examiner that if one of ordinary skill in the art where to select transforming growth factor α or vitamin D metabolite then it would satisfy both requirements of both agents. It is not claimed that both active agents had to be different or the same.

Allowable Subject Matter

9. Claims 131, 132 and 142-148 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

10. Claims 128, 130 and 135-141 stand rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Telephone Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is (571) 272-0613. The examiner can normally be reached from 8AM to 5:30PM Monday to Thursday, and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached at (571) 272-0602. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Konata M. George

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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